

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review
Presented to CON Commission January 24, 2008**

MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS (Please refer to 1.14.08 MDCH staff analysis for additional detail – attached)			
All Identified Issues	Issues Recommended as Requiring Review	Recommended Course of Action to Review Issues	Other/Comments
1. Continued regulation of MRT services/units under CON	Yes	MRT standards to be reviewed in 2008, according to its scheduled three year cycle in the CON review process	CON regulation of MRT services/units appears to be working in Michigan and has broad support.
2. Review requirement of on site radiation oncologist during operation of the unit in a rural facility	Yes	MDCH can gather expert opinion and present a recommendation to the Commission	Two modifications were suggested
3. Review definition to replace an existing MRT unit	Not applicable	MDCH research indicates that the suggested language modification cannot be applicable for all MRT units	
4. Review criteria for expansion with a special purpose MRT unit	No	MDCH supports the current expansion criteria in the MRT standards for a special purpose MRT unit	
5. Review Equivalent Treatment Visit (ETV) weight for IGRT	Yes	MDCH can gather expert opinion and present a recommendation to the Commission	One modification has been suggested
6. Review nuclear particle accelerator technology (proton therapy)	Yes	MDCH can gather expert opinion and present a recommendation to the Commission	Suggestion to gain insight into this alternative treatment option and its future proliferation
7. Review criteria for modification of the Appendices	No	MDCH advisory posted on CON web site addresses the issue	Updated Appendices were presented to the Commission at the December 2007 meeting and given immediate effect

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8. Technical changes in language to be uniform with other CON standards	Yes	Review draft language developed by MDCH staff	
Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft technical changes (#8) for appropriate Commission review and public comment. Additionally, the Department recommends that the Commission request the Department to obtain expert opinion as appropriate, and bring back recommendations for items 2, 5 and 6 at the June 11, 2008 meeting.			

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: January 14, 2008

TO: Irma Lopez

FROM: Umbrin Ateequi

RE: Summary of Public Hearing Comments on Megavoltage Radiation Therapy (MRT) Standards and MDCH Policy Staff Analysis

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Megavoltage Radiation Therapy (MRT) standards on October 31, 2007, with written testimony being received for an additional 7 days after the hearing. The information below is a summary of the testimonies received. The complete oral and written testimonies are included in the January 24, 2008 CON Commission meeting binders. The facilities/organizations represented were as follows:

Oral Testimony Summary

None

Written Testimony Summary

Five individuals provided written testimony, representing five facilities/organizations.

1. *Nelson L. Adamson, MD, Dickinson County Healthcare System:*
Represent the only radiation oncologist on the medical staff in a rural facility, overseeing the radiation oncology service that is a joint venture between Dickinson County and Marquette General Health Systems. The current CON standards, Section 15(B)(iv), state that "All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during operation of the unit(s)." Propose that the wording of this passage be modified to state that "All MRT treatments shall be performed under the supervision of a radiation oncologist. At least one physician will be on site at the geographic location of the unit during the operation of the unit(s)." Believe this minor change would benefit patients and practitioners, while maintaining sufficiently high level of care. This would allow small rural solo practices to maintain adequate staffing, while allowing the radiation oncologist to pursue state, federal, and specialty board mandated requirements for recertification and continuing medical education. Flexibility in scheduling would also allow small rural based practices to accommodate patients that travel great distances for daily radiation treatments,

with less fear of job loss or disruption for patients. Finally, this scheduling flexibility would also allow patients (especially the frail elderly) who have to travel great distances to be seen for follow-up, to be examined at a clinic closer to home, if the radiation oncologist is permitted to make these occasional visits to the community clinic. Since this could potentially lead to abuse, a reasonable approach to ensure that the radiation oncologist is available for patients under his/her care should include some wording that stipulates a minimum requirement. Being present for 80% of the treatment sessions seems reasonable. This would mean being in the clinic 4 out of 5 days.

2. *Kenneth Chu, Ph.D., A.B.R., P.Eng., Chief Medical Physicist, Marquette General Hospital:*

The current CON standards, Section 15(B)(iv), state that “All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during operation of the unit(s).” Propose an additional clause that states, “In cases where there is only a solo radiation oncologist (in rural or micropolitan statistical areas) who does not service any other clinics, a radiation oncologist shall be on-site 90% of the hours when patients are being treated. At least one physician shall be on-site in or immediately available to the MRT unit at all times when patients are being treated.” Understand that the current standard prevents abuse by certain radiation oncologist practices where there may be one radiation oncologist servicing several clinics, and not being available to all the patients most of the time. However, in a solo practice (in rural areas), the current standards do not allow for the radiation oncologist to be ill, late, visit other hospitals for inpatient consults, or attend meetings, except outside of treatment hours.

3. *Robert Meeker, Spectrum Health:*

Support maintaining the MRT standards in their current form, with only minor modifications:

- The current standards include a definition of “Replace/upgrade an existing MRT unit” which is ambiguous. Recommend that this be revised to simply define “Replace an existing MRT unit” as follows: “Replace an existing MRT unit means an equipment change of an existing MRT unit, that requires a change in the radiation safety certificate, proposed by an applicant which results in that applicant operating the same number of non-special and the same number and type of special purpose MRT units before and after the project completion, at the same geographic location.” This resembles the language defining replacement of a CT scanner, as recommended by the CTSAC.
- The existing requirements for adding a special purpose MRT unit to an existing MRT service specify that the special purpose unit must be placed at the same location as the existing MRT units. With the physical expansion of large medical centers, this requirement may be too restrictive. Recommend that the location requirement for adding a special purpose MRT be broadened slightly to parallel the CMS definition of

“campus”, currently defined as within 250 yards of the main hospital building(s).

- With the advent of a new procedure technology, Image Guided Radiation Therapy (IGRT), recommend that it be added to the list of treatments and given an Equivalent Treatment Visit (ETV) weight of 2.5, which is the same as for IMRT.
- In regards to Section 3 of the MRT standards (Modification of the Appendices), recommend that the language be strengthened so that, rather than modification of the data in Appendix A and B requiring Commission action to be updated, such modifications should be required to be performed automatically when more current data becomes available.

4. *Patrick O'Donovan, William Beaumont Hospital:*
Support the continued regulation of MRT services and do not have any recommended changes for 2008.
5. *Sean Gehle, The Michigan Health Ministries of Ascension Health:*
Look forward to participating in a deliberative and open discussion on any potential changes proposed to these standards consistent with the statutory language requiring the Commission to review and, if necessary, revise each set of CON review standards at least every three (3) years. Wholeheartedly support the review of CON standards on the required three year schedule; not as some have suggested, three years from the last time the standard was modified.

Policy Issues to be addressed

Continued regulation of MRT services/units under CON

Based upon the testimonies provided, as well as the goals being promoted by MDCH, the Department supports continued regulation of Megavoltage Radiation Therapy (MRT) Services/Units under CON.

In accordance to the various testimonies received, the Department recommends pursuing minor modifications to the MRT standards.

Requirement of on site radiation oncologist during operation of the unit in a rural facility

Ensuring the delivery of quality health care is one of the main goals of CON regulation. Section 15(B)(iv) of the current MRT standards require that “All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during the operation of the unit(s).” This quality assurance requirement is consistent with criteria required by CON standards for MRT services in other states, such as West Virginia, which mandates that “MRT services will be provided under the direction of an on-site licensed physician who is board-eligible or board-certified by the American Board of Radiology in Radiation Oncology. These personnel must be on-site, when services are being provided.”

However, based on testimony received and the reasons provided, the Department acknowledges the difficulties of a radiation oncologist in a solo practice in a rural or micropolitan statistical area to be on site 100% of the hours when patients are being treated. It has been suggested that while it is desirable that a radiation oncologist be present at all times during treatment administrations, it is not necessary for the daily execution of treatment, and that a regular physician on site may suffice to supervise during certain treatment procedures, as long as that replacement is for a very minimal portion of the hours when patients are being treated. The Department recommends that expert input be considered for the appropriate minimum requirement for a radiation oncologist to be present on site during treatment sessions.

Definition to replace an existing MRT unit

The Department encourages uniformity across the CON standards when appropriate. The current MRT standards define “Replace/upgrade an existing MRT unit” as “an equipment change that results in an applicant operating the same number of non-special and the same number and type of special purpose MRT units before and after the equipment change.”

The Department took into consideration public comment regarding this issue, which suggested that the definition of replacement for MRT units be revised similar to the recently approved replacement definition of a CT scanner by the CON Commission. However, all MRT units do not require a radiation safety certificate. As such, making the “Replace” definition similar to CT will not work for MRT.

Criteria for expansion with a special purpose MRT unit

The current MRT standards states in Section 5(2)(a) that an applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate that “An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant’s non-special MRT units *at the location* where the special purpose unit is to be located.” In order to allow hospitals maximum flexibility, while permitting the use of patient friendly outpatient centers, the following revised language was suggested in public testimony for Section 5(2)(a) of the MRT standards: “An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant’s non-special MRT units *at the same location (or in an adjacent location qualifying as part of the main campus under CMS rules)* where the special purpose unit is to be located.”

The Department does not support this suggestion, as the CON is specific to the facility; if the MRT service is hospital based, then the special purpose unit should be hospital based. The Department supports a continuum of care and keeping the service as one. Special MRT services should be part of a larger general oncology service and not separated. That is also the rationale behind why the current MRT standards require the service to start with high volume non-special MRT units, prior to adding a special purpose unit.

Equivalent Treatment Visit (ETV) weight for IGRT

The Department recognizes that with the advent of new procedure technology, the list of treatments and the corresponding procedure weights should be updated on a regular basis.

Image Guided Radiation Therapy (IGRT) was in fact included, with a definition, in the MRT standards during its last review and approval in 2005. The 2005 MRT SAC was charged with reviewing and updating all of the ETVs. At that time, the SAC determined that IGRT would not be given a separate weight. It was mentioned that IGRT is defined by CMS coding, and that data should be collected for use in the review of the standards in three years. The Department recommends review of this issue and suggests presenting data and analysis gathered from the MDCH Annual Survey to the experts for their recommendation in confirming the appropriate weight for IGRT.

Research indicates that IGRT is complementary to IMRT. IMRT is used to improve the radiation delivery precision and IGRT is used to improve the radiation delivery accuracy. IGRT combines a new form of scanning technology, which allows planar or X-ray Volume Imaging, with IMRT. This enables physicians to adjust the radiation beam based on the position of the target tumor and critical organs, while the patient is in the treatment position. With IGRT, higher doses of radiation can be focused and delivered directly to tumors and cancer cells, maximizing effectiveness. IGRT allows the precise delivery of radiation to tumors in real time while allowing normal tissues to receive minimal radiation. This procedure sets the stage for allowing the radiation oncologist to safely increase the radiation dose to tumors while minimizing side effects. Clinical studies have indicated that higher doses of radiation significantly improve local tumor control.

Nuclear particle accelerator technology (proton therapy)

According to a recent New York Times article (December 26, 2007), medical centers are looking to turn nuclear particle accelerators into the latest weapons against cancer:

“The machines accelerate protons to nearly the speed of light and shoot them into tumors. Scientists say proton beams are more precise than the X-rays now typically used for radiation therapy, meaning fewer side effects from stray radiation and, possibly, a higher cure rate. But a 222-ton accelerator, and a building the size of a football field with walls up to 18-feet thick in which to house it, can cost more than \$100 million. Until 2000, the United States had only one hospital-based proton therapy center. Now there are five, with more than a dozen others announced. Still more are under consideration. Some experts say there is a vast need for more proton centers. But others contend that the arms race mentality has taken hold, as medical centers try to be first to take advantage of the prestige, and the profits, a proton site could provide...

On the horizon is therapy using beams of carbon ions, which are said to be even more powerful in killing tumors. Touro University says it will build a combined proton and carbon therapy center outside San Francisco, to open as early as 2011. The Mayo Clinic is also seriously considering one. Such centers will cost even more – as much as \$300 million.”

It is unclear at this time if this treatment option is covered by the definition of MRT; Radiation Safety is currently reviewing the issue. The Department recommends expert review of this technology as an alternative treatment option to radiation therapy and insight into the potential for its proliferation in Michigan. Currently, there are no hospital-based proton therapy centers in Michigan.

Criteria for modification of the Appendices

On September 4, 2007, an advisory was posted on the CON web site that states, in part, "...the Department will utilize the most current submitted, verifiable and complete data available from the Michigan Cancer Surveillance Program for initiation of MRT and PET services..." This makes the most recent data available to all applicants.

The Department most recently updated the Duplication Rates and Duplication Factors using Hospital and Registry Reporting Sources (Appendix A), and the Distribution of MRT Courses by Treatment Visit Category (Appendix B). These updated appendices of the MRT standards were presented at the December 11, 2007 CON Commission meeting and given immediate effect.

Technical Changes and Updates

The Department is systematically modifying all CON review standards to achieve uniformity and to accommodate the CON application on-line system.